

REMARKS

Claims 20, 30, 32, 33, 35, 43 and 44 are pending. Applicants have reviewed the current Office Action and respectfully traverse all grounds of rejection for the reasons that follow.

Rejections Under 35 U.S.C. § 112

Claims 20, 30, 32, 33 and 35 stand rejected under 35 U.S.C. § 112, first paragraph, for lacking enablement allegedly because the application fails to show a detected mRNA that is 98% identical to SEQ ID NO:1587.

The specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *Genentech, Inc. v. Novo Nodisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997).

The Examiner's requirement to restrict the claims to the exact sequence of SEQ ID NO:1587 is unduly limiting. Claim 20 is directed to a method for diagnosing colon cancer which includes detecting an expression product having the nucleotide sequence of SEQ ID NO:1587. Claim 35 is directed to a similar method of detection which includes determining the expression level of a nucleic acid having the nucleotide sequence of SEQ ID NO:1587 in a patient sample. No percent identity is recited. Therefore, claims 20 and 35 do not fall under the "genus" of sequences having at least 98% identity as alleged by the Examiner. Accordingly, the specification sufficiently enables one skilled in the art to make and use the invention as claimed. Therefore, withdrawal of this ground of rejection is respectfully requested.

Rejections Under 35 U.S.C. § 102

Claims 43 and 44 stand rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by McGarrity et al., *Gut* 32:1121-26 (1991) as evidenced by Billingsley et al., *Proc. Natl. Acad. Sci. USA* 82:7585-89 (1985). The Examiner alleges that McGarrity et al. describe a method of detecting a protein that is identified as either calcineurin, calmodulin kinase II or a novel calmodulin binding protein. The Examiner further alleges that Billingsley et al. provides evidence that the protein described by McGarrity et al. likely was calcineurin and that the molecular weight given by McGarrity et al. appears to be a mischaracterization.

When lack of novelty is based on a printed publication that is asserted to describe the same invention, a finding of anticipation requires that the publication describe all of the elements of the claims. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1349, 48 U.S.P.Q.2d 1225, (Fed. Cir. 1998) (*quoting Shearing v. Iolab Corp.*, 975 F.2d 1541, 1544-45, 24 U.S.P.Q.2d 1133, 1136 (Fed. Cir. 1992)) (*accord Elan Pharmaceuticals, Inc. v. Mayo Foundation for medical Research and Education*, 304 F.3d 1221, 1228-1229 (Fed. Cir. 2002)). To establish inherency it must be clear:

[T]hat the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.

Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991). Furthermore, inherency must be established with certainty.

An inherent limitation is one that is necessarily present; invalidation based on inherency is not established by “probabilities or possibilities.”

Scaltech, Inc. v. Retec/Tetra, LLC., 178 F.3d 1378, 1384, 51 U.S.P.Q.2d 1055, 1059 (Fed. Cir. 1999) (*accord Elan Pharmaceuticals, Inc.* 304 F.3d at 1228).

Applicants submit that the Examiner has not met this burden to establish inherent anticipation. Here, it cannot be said with certainty that the protein of McGarrity et al. is the same as that claimed. As shown in Applicants’ previous response, its molecular weight is characterized differently by McGarrity et al. and Billingsley et al. A conclusory assertion that “the molecular weight given by McGarrity appears to be a mischaracterization” is insufficient to satisfy the required burden. The Examiner further concedes that the required certainty is absent by stating that the protein of McGarrity et al. “was likely” calcineurin and that McGarrity’s molecular weight “appears” to be a mischaracterization (Office Action at page 5). Such language leaves doubt.

Absent a showing to the contrary, the Examiner’s own uncertainties, the difference in molecular weight and the fact that McGarrity et al. could not conclude that the described protein was PPP3CC make clear that the rejection is based on probabilities or possibilities and not on certainty as required by Federal Circuit precedent. Therefore, it cannot be concluded that the

missing descriptive matter is necessarily present in McGarrity et al.. Accordingly, the cited reference fails to anticipate the invention as claimed and withdrawal of this ground of rejection is respectfully requested.

CONCLUSION

In light of the Amendments and Remarks herein, Applicant submits that the claims are in condition for allowance and respectfully request a notice to this effect. Should the Examiner have any questions, he is invited to call the undersigned attorney.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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